

K952614

DENTSPLY

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AUG 13 1996

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August 8, 1996

301-480-3002
TELEFAXED AND
EXPRESS MAIL

Mr. Greg Singleton (HFZ-480)
Food and Drug Administration
Center for Devices and Radiological Health
9200 Corporate Boulevard
Rockville, MD 20850

AMENDMENT #3

K952614, Jeltrate® PLUS™ Antimicrobial Dustless Alginate
Impression Material

FD-400 (Rev. 1-85)

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RECEIVED

This letter is in response to your telephone call to me this afternoon.

As you requested, attached is a revised **510(k) SUMMARY** for K952614, changing the claim to read:

Jeltrate® PLUS™ eliminates up to 99% of viable surface microorganisms after water rinsing the impression for just 15 seconds.

If you have any additional questions, please don't hesitate to contact me.
Thank you.

Sincerely,



P. Jeffery Lehn
Associate Director
Corporate Compliance

Attachment



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510(k) SUMMARY

NAME & ADDRESS: DENTSPLY International, 570 West College Avenue, York, PA 17404
CONTACT: P. Jeffery Lehn
PHONE: (717) 845-7511 FAX: (717) 849-4343
DATE PREPARED: August 8, 1996

TRADE OR PROPRIETARY NAME: JELTRATE® PLUS™ IMPRESSION MATERIAL

COMMON OR USUAL NAME: Impression Material

CLASSIFICATION NAME: Impression Material, 21 CFR, 872.3660

LEGALLY MARKETING DEVICE: Jeltrate PLUS Impression Material K883842

DESCRIPTION OF DEVICE: JELTRATE PLUS is dust free, fast setting, and helps protect staff from infection due to cross-contamination prior to soaking the impression.

INTENDED USE: JELTRATE PLUS is used for all routine dental impressions.

TECHNOLOGICAL CHARACTERISTICS: There has been no change in composition, design, material, packaging, function or manufacture of Jeltrate® PLUS™ Antimicrobial Dustless Alginate Impression Material (K883842). This submission represents only an additional claim.

We believe the conclusions of the study conducted support the additional claim that JELTRATE PLUS eliminates up to 99% of viable surface microorganisms after water rinsing the impression for just 15 seconds.